REMARKS

Claims 1-4, 6-47 and 49-75 were pending in the present application, and stand rejected. It appears that claims 76-82 were withdrawn, but not formally cancelled. By this amendment, claims 62, 64 and 76-82 have been cancelled, and claims 1, 13, 14, 16, 36, 38, 60, 61, 63, 65, 66, 67, 69, 70, and 72 have been amended. This application now includes claims 1-4, 6-47, 49-61, 63, and 65-75.

Reconsideration of the rejection of pending claims 1-4, 6-47 and 49-61, 63, and 65-75 is respectfully requested.

Claims 13, 16, and 38 were objected to because of formalities. Claims 13, 16, and 38 have been amended to address the Examiner's concerns. Accordingly, it is respectfully requested that the objection to claims 13, 16 and 38 be withdrawn.

Claims 1-47 and 49-75 were provisionally rejected on the grounds of obviousness-type double patenting with respect to claims 1-42 of copending application 10/907,906. As an administrative expedient in order to advance the prosecution of the present application, submitted herewith is a terminal disclaimer directed to copending application 10/907,906. Accordingly, it is respectfully requested that provisional rejection of claims 1-47 and 49-75 on the grounds of obviousness-type double patenting be withdrawn.

Claims 1-4, 6-12, 14-15, 36, 37, 49-55, 60-62 and 68-74 were rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer, et al. (US 5,127,916; hereinafter Spencer) in view of Gillick, et al. (US 2003/0028236; hereinafter, Gillick).

Claim 1, as amended, recites in part:

> "a localization wire positioned to extend from the handle and into the lumen of the cannula, the localization wire having a distal end that is positioned near the insertion tip and contained within the lumen when the cannula is in the insertion position, wherein the localization

> wire comprises at least one anchor adapted to hold the localization wire in the tissue mass, the cannula and the localization wire being configured such that **each** of the at least one anchor remains **completely contained** in the cannula when the cannula is in the insertion position prior to the cannula being moved to the retracted position; and
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> an actuator in operable communication with the cannula and configured for operation between a charged condition and a discharged condition to **retract the cannula** toward the retracted position to **expose the distal end of the localization wire** to the tissue mass and **expose each of the at least one anchor to the tissue mass**, without inducing movement of the localization wire, and with the cannula being removable from the localization wire in its entirety. (Emphasis added).

Support for the amendments to claim 1 may be found in Applicants' specification, for example, at paragraphs 0073, 0074 and 0076, and Figs. 3, 6, 8, and 9.

In contrast to claim 1, Spencer discloses with respect to Fig. 3, "a stranded needle structure 30 having a proximal end 31 and a distal end 32 and which includes a short inner cannula member 33 which is attached to the core wire 16 at its end 35. The needle structure 30 further includes a short wire member 36.... [that] includes a free end 37 defining a barb or hook which is adapted to anchor the needle within body tissue." Spencer, column 5, lines 46-55. Spencer further discloses at column 6, lines 38-44, "Referring to FIGS. 11 and 11A, the needle guide assembly 60 is illustrated with the barb 36 in the extended position wherein the **needle wire structure 30 has withdrawn** back into the cannula 11, moving the inner cannula 33 towards the right in FIGS. 11 and 11A, permitting the barb 36 to pass through the opening 14 in the cannula 11 for deployment." Thus, as disclosed in Spencer, the localization wire 30 is withdrawn in cannula 11 to deploy the barb through opening 14 in outer cannula 11 when the cannula is in the insertion position, and the deployment of the barb anchor occurs before retraction of the cannula.

This also is necessarily so in the Spencer embodiment of Figs. 15-16A, wherein the distal end 13 is not maintained in the lumen of the cannula 11 prior to cannula retraction, and the size of the side opening 14 relative to the barb 36 is such that in order to achieve the configuration as shown in Fig. 16, the localization wire 19 must necessarily be retracted relative to outer cannula 11. Moreover, as stated in Spencer, "FIG. 16 illustrates the needle positioned to provide a temporary anchoring by the retractable barb 36 during imaging to confirm that a lesion has been precisely located. FIG. 16A illustrates withdrawal of the outer cannula 11 **following** confirmation of localizing a lesion whereby both barbs are deployed in the body tissue." (Spencer, column 8, lines 35-41; emphasis added).

Thus, in the embodiments of Spencer, and in contrast to claim 1, as amended, the retractable barb anchor is exposed to the tissue mass prior to retraction of the outer cannula 11.

The Examiner also recognizes that Spencer does not expressly teach an actuator in operable communication with the cannula and operable between a charged condition and a discharged condition to retract the cannula to expose the distal end of the localization wire to the tissue mass. In this regard, the Examiner relies on Gillick.

Gillick at paragraph 0028 discloses, "The control device 20 includes a control knob 32 (FIG. 1) which can be manipulated by the physician to retract the restraining sheath 26 **to deploy the stent 30** in the body vessel. This control knob 32 moves along a slot 34 in a top plate 36 which forms part of the housing 22." (Emphasis added). While Gillick is related to medial devices, Gillick has nothing to do with implanting a localization wire within a tissue mass. Moreover, as disclosed in Gillick paragraph 0032, "As can be seen in FIGS. 6 and 7, the stent 30 is mounted onto a mounting component 58 located at the distal end 28 of the

restraining sheath 26. This mounting component 58 is in turn attached to an inner member 60 which extends coaxially with the restraining sheath 26 and is mounted within the control device 20. This inner member 60 and mounting component 58 also form a part of the catheter portion of the device 20. This inner member 60 extends through an opening 62 in the housing 22 to a leur fitting 64 which connects to the proximal end 66 of the inner member 60. This inner member 60 serves as a conduit for receiving a guide wire 68 (see FIGS. 6 and 7) utilized to deliver the medical device into the patient's artery." (Emphasis added). Thus, Gillick discloses a device that may be guided by a localization wire, but is not directed to a device for deploying a localization wire.

As such, one of ordinary skill in the art would not be motivated to modify the arrangement of Spencer with the stent deployment device of Gillick in attempting to achieve the present invention. In addition, in any attempt to achieve the invention as recited in claim 1 by the combination of Spencer and Gillick, significant change in the structure and function of the combined elements of Spencer and Gillick would have been required. Thus, for reasons set forth above, the improved structure provided by the present invention over that of Spencer in view of Gillick is more than the predictable use of the elements of Spencer in view of Gillick according to their established functions, and thus is not obvious. See *KSR International Co. v. Teleflex Inc. (KSR)*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007).

Moreover, even if Spencer and Gillick could somehow be combined in an attempt to achieve the present invention, (although it is contended that it would not be obvious to do so), for reasons set forth above the combined structure would not satisfy all the limitations of claim 1.

Accordingly, it is respectfully submitted that claim 1 is patentable over the cited references.

Claims 2-4, 6-12, 14, and 15 depend, directly or indirectly, from claim 1, and thus are patentable for at least the reasons set forth above with respect to claim 1.

Independent claim 36, as amended, recites in part:

> "a localization wire located within the lumen and having a distal end near the insertion tip when the cannula is in the insertion position, wherein the localization wire comprises at least one anchor adapted to hold the localization wire in the tissue mass, the cannula and the localization wire being configured such that each of the at least one anchor remains completely contained in the cannula when the cannula is in the insertion position prior to the cannula being moved to the retracted position; and
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> an actuator operable between a charged condition and a discharged condition to effect movement of the cannula relative to the localization wire;
>
> wherein the handle, the cannula, the localization wire, and the actuator form a self-contained implanting apparatus for implanting the localization wire into the tissue mass, whereby the cannula is inserted into the tissue mass and the actuator is placed in the discharged condition to effect movement of the cannula relative to localization wire to expose the distal end of the localization wire to the tissue mass and expose each of the at least one anchor to the tissue mass, without inducing movement of the localization wire, and with the cannula being removable from the localization wire in its entirety. (Emphasis added).

Support for the amendments to claim 36 may be found in Applicants' specification, for example, at paragraphs 0073, 0074 and 0076, and Figs. 3, 6, 8, and 9.

Independent claim 36 is patentable for substantially the same reasons set forth above with respect to claim 1.

Claims 37 and 49-55 depend, directly or indirectly, from claim 36, and thus are patentable for at least the reasons set forth above with respect to claim 36.

Independent claim 60 is directed to a method of percutaneously implanting a localization wire into a tissue mass, and as amended, recites in part:

completely containing each of the at least one anchor in the lumen of the cannula when the cannula is in the insertion position prior to the cannula being moved to the retracted position;

inserting the insertion tip of the cannula and the localization wire into the tissue mass; and

operating the actuator to retract the cannula to expose ~~a portion of~~ the distal end of the localization wire to the tissue mass and expose each of the at least one anchor to the tissue mass, without inducing movement of the localization wire. (Emphasis added).

Support for the amendments to claim 60 may be found in Applicants' specification, for example, at paragraphs 0073, 0074 and 0076, and Figs. 3, 6, 8, and 9.

Independent claim 60 is patentable for substantially the same reasons set forth above with respect to claim 1.

Claims 61, (62 cancelled), and 68-74 depend, directly or indirectly, from claim 60, and thus are patentable for at least the reasons set forth above with respect to claim 60.

Accordingly, it is respectfully submitted that now pending claims 1-4, 6-12, 14-15, 36, 37, 49-55, 60, 61 and 68-74 are patentable under 35 U.S.C. 103(a) over Spencer in view of Gillick.

Claims 16-35, 38-47, 56-59, 63-67 and 75 were rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer in view of Gillick, and further in view of Niezink, et al. (US 5,273,532; hereinafter Niezink).

Niezink discloses a device for quickly and easily inserting an object, e.g., a transponder, into an animal. (Niezink, column 4, lines 55-66). As is apparent from Niezink, there is no concern as to the exact placement of the "object", but rather, deployment of the object 14 occurs then the trigger is released when the external trigger component 6 comes in contact with the animal's skin. As such, the structure of Niezink is not suitable for use with

the accurate placement of a localization wire at a specific location in a tissue mass, such as to mark the precise location within a tissue mass to be biopsied.

Also, in Niezink it is noted that deployment requires the presence of a push rod 24 that is positioned in the lumen of the needle 3 so as to force the object 14 through and out of the lumen. (Niezink Figs. 2a-2b). Due to the presence of the push rod 24, however, the structure of Niezink would not facilitate the reception of a localization wire in and through the lumen of needle 3. Further, due to the elongate and flexible nature of a localization wire, even if a localization wire was somehow positioned in the needle 3 (although it is submitted that it would not be obvious to do so), the push rod concept disclosed in Niezink would likely be ineffective in deployment of the localization wire, since such an approach would be similar to trying to push a rope, and accurate placement of the anchor would not be achieved.

Accordingly, it is respectfully submitted that it would not be obvious to modify the combined structures of Spencer in view of Gillick with the transponder deployment mechanism of Niezink in attempting to achieve the invention as recited in claims 16-35, 38-47, 56-59, 63-67 and 75. Also, in an attempt to achieve the invention as recited in claims 16-35, 38-47, 56-59, 63-67 and 75 by the combination of Spencer in view of Gillick, and further in view of Niezink, significant change in the structure and function of the combined elements of Spencer in view of Gillick, and further in view of Niezink would have been required. Thus, for reasons set forth above, the improved structure provided by the present invention over that of Spencer in view of Gillick, and further in view of Niezink is more than the predictable use of the elements of Spencer in view of Gillick, and further in view of Niezink according to their established functions, and thus is not obvious. See *KSR International Co. v. Teleflex Inc. (KSR)*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007).

Further, claims 16-35 depend, directly or indirectly, from claim 1, and thus are patentable for at least the reasons set forth above with respect to claim 1, since Niezink does not overcome the deficiencies of Spencer in view of Gillick with respect to claim 1.

In addition, at least some of claims 16-35 would be patentable in its own right.

For example, claim 27 recites, "The apparatus of claim 25, wherein the collar forms a key and the apparatus further comprises a keyway shaped for receiving the key, and wherein the key is unaligned from the keyway when the actuator is in the charged condition and is aligned with the keyway when the actuator is in the discharged condition." As background, claim 18, from which claim 27 indirectly depends, recites, "actuator comprises a trigger operable between a ready position and a release position for controlling the operation of the biasing element" and intervening claim 25 further recites, "wherein the spring is located within the hollow interior and extends between the end and a collar extending from the cannula." The Examiner recognizes that none of the cited references discloses the arrangement as recited in claim 27, but the Examiner asserts that such is an obvious variant of that which is disclosed in Niezink. Applicants respectfully disagree.

The Examiner references components 12, 16 and 22 as corresponding to a trigger. Component 16, however, is not a trigger, but rather is a release to remove the needle from the needle holder. (Niezink column 5, lines 26-31). In Niezink, component 12 (Fig. 2c) and component 22 (Fig. 4d) are triggers used in the respective embodiments to release the respective needle holder 2, 20 to retract the needle 3.

Notwithstanding, none of components 12, 16, and 22 form a structure that is configured like the structure recited in claim 27. Moreover, the structure as recited in claim 27 advantageously provides a built-in safety feature that is not provided or suggested by the

structure in Niezink. In Niezink, the release of either of the triggers 12 and 20, which in turn releases the respective compressed spring, occurs due to a forward thrust of the Niezink apparatus. Such a structure as disclosed in Niezink does not address the possibility of inadvertent release by an inadvertent axial (thrust) force being applied to the trigger mechanism to prematurely deploy the object 14.

In contrast to Niezink, in claim 27 the collar forms a key and the apparatus further comprises a keyway shaped for receiving the key, and wherein the key is unaligned from the keyway when the actuator is in the charged condition and is aligned with the keyway when the actuator is in the discharged condition. Such a structure avoids the possibility of an inadvertent discharge based on an inadvertent application of an axial (thrust) force against the trigger. As such, the structure recited in claim 27 is not an obvious variant of the structure disclosed in Niezink.

Accordingly, claim 27 is patentable in its own right.

Claims 28 and 29 depend from claim 27, and thus are further patentable for at least the additional reasons set forth above with respect to claim 27.

In addition, claim 28 recites, "The apparatus of claim 27, wherein the trigger is **rotatably mounted** to the handle and operably coupled to the key such that rotation of the trigger aligns the key with the keyway to thereby release the spring." (Emphasis added). Thus, claim 28 makes even more clear the advantage of the structure of claims 27 and 28 over the structure of Niezink by the further recitation of the rotational aspect of the trigger such that rotation of the trigger aligns the key with the keyway to thereby release the spring. Such a structure avoids the possibility of an inadvertent discharge based on an inadvertent application

of an axial (thrust) force against the trigger. As such, the structure recited in claim 28 is not an obvious variant of the structure disclosed in Niezink.

Claims 38-47 and 56-59 depend, directly or indirectly, from claim 36, and thus are patentable for at least the reasons set forth above with respect to claim 36, since Niezink does not overcome the deficiencies of Spencer in view of Gillick with respect to claim 36.

In addition, at least some of claims 38-47 and 56-59 would be patentable in its own right.

For example, claim 44 recites, "The apparatus of claim 42, wherein the collar forms a key and the apparatus further comprises a keyway shaped for receiving the key, and wherein the key is unaligned from the keyway when the actuator is in the charged condition and is aligned with the keyway when the actuator is in the discharged condition."

Claim 44 is patentable in its own right for substantially the same reasons set forth above with respect to claim 27. In summary, in contrast to Niezink, in claim 44 the collar forms a key and the apparatus further comprises a keyway shaped for receiving the key, and wherein the key is unaligned from the keyway when the actuator is in the charged condition and is aligned with the keyway when the actuator is in the discharged condition. Such a structure avoids the possibility of an inadvertent discharge based on an inadvertent application of an axial (thrust) force against the trigger. As such, the structure recited in claim 44 is not an obvious variant of the structure disclosed in Niezink.

Accordingly, claim 44 is patentable in its own right.

Claims 45 and 46 depend from claim 44, and thus are further patentable for at least the additional reasons set forth above with respect to claim 44.

In addition, claim 45 recites, "The apparatus of claim 44, wherein the trigger is rotatably mounted to the handle and operably coupled to the key such that rotation of the trigger aligns the key with the keyway to thereby release the spring". Thus, claim 45 makes even more clear the advantage of the structure of claims 44 and 45 over the structure of Niezink by the further recitation of the rotational aspect of the trigger such that rotation of the trigger aligns the key with the keyway to thereby release the spring. Such a structure avoids the possibility of an inadvertent discharge based on an inadvertent application of an axial (thrust) force against the trigger. As such, the structure recited in claim 45 is not an obvious variant of the structure disclosed in Niezink.

Claims 63-67 and 75 depend, directly or indirectly, from claim 60, and thus are patentable for at least the reasons set forth above with respect to claim 60, since Niezink does not overcome the deficiencies of Spencer in view of Gillick with respect to claim 60.

Accordingly, it is respectfully submitted that now pending claims 16-35, 38-47, 56-59, 63, 65-67 and 75 are patentable under 35 U.S.C. 103(a) over Spencer in view of Gillick, and further in view of Niezink.

Claim 13 was rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer in view of Gillick, and further in view of Negus, et al. (US 6,241,665; hereinafter, Negus).

Claim 13 depends indirectly from claim 1, and thus is patentable for at least the reasons set forth above with respect to claim 1, since Negus does not overcome the deficiencies of Spencer in view of Gillick with respect to claim 1.

In addition, claim 13 as amended recites, "The apparatus of claim 12 wherein the imageable portion comprises etched portions spaced at intervals along the localization wire"

(emphasis added), which is not disclosed, taught or suggested by Negus or the other cited references.

Accordingly, for at least the reasons set forth above, it is respectfully submitted that claim 13 is patentable under 35 U.S.C. 103(a) over Spencer in view of Gillick, and further in view of Negus.

For the foregoing reasons, Applicants submit that the cited references do not render obvious the subject matter of the pending claims. The pending claims are therefore in condition for allowance, and Applicants respectfully request withdrawal of all rejections and allowance of the claims.

In the event Applicants have overlooked the need for an extension of time, an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby conditionally petition therefor and authorize that any charges be made to Deposit Account No. 50-5242, RONALD K. AUST, P.C.

Should any question concerning any of the foregoing arise, the Examiner is invited to telephone the undersigned at (317) 894-0801.

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